

AUG 27 2004**510(k) SUMMARY****SUBMITTED BY**

Wendy Spielberger
Lead Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Vertebral Body Replacement Device
Common/Usual Name: Vertebral Body Replacement Device
Product Classification: Class II
Proprietary Name: Expandable PEEK VBR Implant

PREDICATE DEVICE

Predicate device information is included in this premarket notification.

INDICATIONS-FOR-USE

The Expandable PEEK VBR Implant is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Expandable PEEK VBR Implant is also indicated for treating fractures of the thoracic and lumbar spine. The Expandable PEEK VBR Implant is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

DEVICE DESCRIPTION

The Expandable PEEK VBR Implant is an expandable device constructed of Polyetheretherketone, medical grade (PEEK OPTIMA™ LT1) as described by ASTM F-2026. The tantalum markers used for this product are made to the voluntary standard ASTM F-560. The Expandable PEEK VBR Implant is inserted between vertebral bodies in the posterior thoracolumbar spine from T1 to L5. Following insertion into the surgical site, the implant may be left undistracted or may be expanded via a ratcheting mechanism. When expanded, a reinforcement clip is inserted into the implant to aid in maintaining height. The radiolucent PEEK material allows visualization of the defect site on radiograph to assess bone growth.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the Expandable PEEK VBR Implant is considered substantially equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Wendy Spielberger, RAC
Lead, Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618

Re: K040928

Trade/Device Name: Expandable PEEK VBR Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 13, 2004
Received: August 16, 2004

Dear Ms. Spielberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 040928

Device Name: **Expandable PEEK VBR**

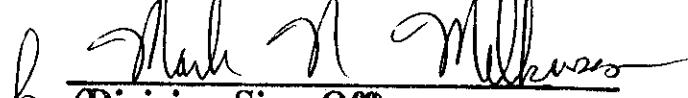
Indications-For-Use:

The Expandable PEEK VBR Implant is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Expandable PEEK VBR Implant is also indicated for treating fractures of the thoracic and lumbar spine. The Expandable PEEK VBR Implant is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

Prescription Use <u>X</u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Mark M. Miller
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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